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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/664,513 | 09/16/2003 | Marc K. Hellerstein | 416272003700 | 4651 |

20872 7590 10/20/2005
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EXAMINER

MARTIN, PAUL C

ART UNIT PAPER NUMBER

1655

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|------------------------|--|----------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 10/664,513 | | HELLERSTEIN, MARC K. | |
| | Examiner | | Art Unit | |
| | Paul C. Martin | | 1655 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) 4-7, 9-20, 27-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8 and 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/23/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-58 are pending in this application.

Election/Restrictions

Applicant's election with traverse of Group I (Claims 1-29) in the reply filed on 09/19/05 is acknowledged. The traversal is on the ground(s) that:

1) It would not be an undue burden on the Office to search all of the pending claims.

This is not found persuasive because of the reasons discussed in the previous restriction. The Groups are distinct inventions from each other and rely upon different method steps, so that the practice of one method would not necessarily lead to another. Therefore, a search and examination of all the Groups in one application would result in an undue burden since the nine searches would not necessarily be co-extensive.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's election with traverse of Group I (Claims 1-29) and of the species, wherein: "isotopically labeled precursor molecule" is elected as the species H²-labeled glucose, "living system" is elected as an animal, and "mitochondrial molecule" is elected as deoxyribonucleic acid, is acknowledged.

Art Unit: 1655

Applicant's election with traverse of species in the reply filed on 09/19/05 is acknowledged. The traversal is on the ground(s) that:

2) That the species election would not present an undue search burden on the Office.

This is not found persuasive because of the reasons discussed in the previous restriction, and because Applicant did not supply evidence that the species are not patentable distinct. All the possible permutations of isotopically labeled precursor molecules, living systems, mitochondrial molecules, drug agents and subspecies thereof would present a serious search burden on the Examiner.

Claims 30-58 are hereby withdrawn from examination on the merits as they are directed toward non-elected inventions.

Because claims 4-7, 9-20, and 27-29 are directed toward non-elected species, these claims are hereby withdrawn from examination on the merits.

Claims 1-3, 8, and 21-26 were examined on their merits.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because of the legal phraseology "...by this means". Correction is required. See MPEP § 608.01(b).

Specification

The use of the trademark Sprague-Dawley™ has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Double Patenting

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 8, 21, 23, 24 and 26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-6 and 11 of U.S. Patent No. 6,010,846. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims 1-2, 8, 21, 23, 24 and 26 are "anticipated" by claims 1, 4-6, and 11 of U.S. Patent No. 6,010,846 because the scope of the claims 1-2, 8, 21, 23, 24 and 26 falls entirely within the scope of claims 1, 4-6, and 11 of U.S. Patent No. 6,010,846.

Claims 1-3, 8, and 21-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5-8, 13, 26, 29 and 31 of copending Application No. 10/701,990. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-3 and 8 are "anticipated" by claims 27 and 31 of Application No. 10/701,990 and claims 22-26 are made obvious by claims 27 and 31.

Double Patenting

Claims 1-3 and 8 are "anticipated" by claims 27 and 31 of Application No. 10/701,990 because the scope of the claims 1-3 and 8 of the instant Application fall entirely within the scope of claims 27 and 31 of 10/701,990.

Although claims 27 and 31 of 10/701,990 do~~x~~ not specifically teach the particulars of instant claims 22-26, i.e., wherein the isotopically labeled precursor molecule is administered orally or wherein the living system is an animal, mammal, rodent or human, the ordinary artisan would have been motivated to administer the labeled precursor molecule orally to an animal, mammal, rodent, or human in order to assess the metabolic processing of the isotopically labeled precursor molecule. It is clear from claim 1 of 10/701,990 that the labeled sugars administered to an "individual", which is the genus of humans or rodents for example, thereby making obvious the species of humans and rodents.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 8, and 21-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Hellerstein (5,910,403).

Hellerstein teaches a method of administering the isotopically labeled precursor molecule H²-labeled glucose to both animal (Rat) and human subjects for a time sufficient for the label to be incorporated into deoxyribonucleic acid in the subject, (Column 10, Lines 46-67 and Column 11, Lines 1-27), measuring the isotopic content, pattern, rate of change of isotopic content or pattern of the deoxyribonucleic acid (Column 10, Lines 65-67 and Column 11, Lines 20-22), and calculating the rate of synthesis of deoxyribonucleic acid in the subject (Table 3 and Column 16, Lines 6-7 & Fig.8)

Art Unit: 1655

Hellerstein teaches the step of measuring the isotopic content, pattern, rate of change of isotopic content or pattern of the deoxyribonucleic acid by Gas Chromatograph Mass Spectrometry. (Column 10, Line 67 & Fig.2 and Column 11, Line 21).

Hellerstein teaches the method wherein the isotopically labeled precursor molecule is administered orally. (Column 9, Line 36).

Claims 1, 2, 8, 21, 23, 24 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Hellerstein. (6,010,846)

Hellerstein teaches a method of administering an isotopically labeled precursor molecule to human (animal, mammal) subjects with a detectable amount of the label to be incorporated into deoxyribonucleic acid in the subject, (Column 28, Lines 20-35; Column 25, Lines 6-16), measuring the isotopic content, pattern, rate of change of isotopic content or pattern of the deoxyribonucleic acid (Column 24, Lines 59-67; Column 25, Lines 1-2 and Fig.2 and Column 25, Lines 24-26), and calculating the rate of synthesis of deoxyribonucleic acid in the subject (Table 2, Column 29, Lines 34-47 and Fig. 7)

Hellerstein teaches the step of measuring the isotopic content, pattern, rate of change of isotopic content or pattern of the deoxyribonucleic acid by Gas Chromatograph Mass Spectrometry. (Column 25, Lines 1-2, 24-25 and Fig. 2).

Art Unit: 1655

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one with ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Martin
Examiner
Art Unit 1655

9/30/05

PATRICIA LEITH
PRIMARY EXAMINER
